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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,019	07/19/2001	Ian Jeffrey Evans	PPD 50355/UST	2062

22847 7590 04/05/2005

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,019	EVANS ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *SEARCH RESULTS*.

DETAILED ACTION

1. Applicant's election without traverse of Group V (claims 1-15) and SEQ ID NO:5 in the reply filed on 27 September 2005 is acknowledged.

2. In the claims filed 27 September 2004, claims 16-19 should be indicated as "Cancelled" not "deleted".

Claim Objections

3. Claims 6-9 and 14 are objected to because of the following informalities:

In claim 6, lines 5 and 12, "No." should be replaced with --NO:--.

Claims 7-9 start with an improper article.

In claim 14, line 2, "comprising" should be replaced with --wherein the method comprises--.

4. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Parent claims 1-6 are drawn to a nucleic acid of SEQ ID NO:5, a specific portion of SEQ ID NO:5 or that hybridize to SEQ ID NO:5. Claim 9 is drawn to a nucleic acid of any of those claims wherein the nucleic acid is modified. Thus, claim 9 fails to incorporate all of the limitations of the parent claims.

5. Claim 2is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

8. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to polynucleoitdes, which are products of nature.

Claims 1-6, as written, do not sufficiently distinguish over nucleic acids as they exist in nature because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that the claims be modified to refer to the hand of the inventor, *e.g.* by replacing "A" in claims 1-6 with --An isolated--. See MPEP 2105.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 5-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:5, plants transformed with it, and a method of using it to make microbe-resistant plants, does not reasonably provide enablement for nucleic acids that hybridize to SEQ ID NO:5, plants transformed with them and a method of using them to make microbe-resistant plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a multitude of nucleic acids that hybridize to SEQ ID NO:5, plants transformed with them and a method of using them to make microbe-resistant plants.

The instant specification, however, only provides guidance for isolation of DNAs encoding Dahlia anti-microbial proteins by PCR and hybridization - Dm1 (SEQ ID NO:5, which encodes SEQ ID NO:12), Dm2.18 (SEQ ID NO:1, which encodes SEQ ID NO:8), Dm2.1 (SEQ ID NO:2, which encodes SEQ ID NO:9), Dm2.3 (SEQ ID NO:3, which encodes SEQ ID NO:10) and Dm2.5 (SEQ ID NO:4, which encodes SEQ ID NIO:11) (example 1); expression of what is possibly SEQ ID NO:5 in Arabidopsis, tomato and maize (examples 2-6). It is unclear what is expressed in the plants because pg 2, lines 3-5 states that Dm-AMP1 is taught in WO 93/05153;

the examples discuss expression of DM-AMP1 in plants, but pg 11, line 14 indicates that the sequence of SM-AMP1 is SEQ ID NO:5; a search of SEQ ID NO:5 did not identify it as the sequence taught in WO 93/05153.

The instant specification fails to provide guidance for a multitude of nucleic acids that hybridize to SEQ ID NO:5, plants transformed with them and a method of using them to make microbe-resistant plants.

The instant specification fails to teach where to find or how to make nucleic acids that hybridize to SEQ ID NO:5 within the full scope of the claims.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:12 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain anti-microbial activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

The sensitivity of proteins to alterations in even a single amino acid in a sequence is exemplified by Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252), who teach that a replacement of aspartic acid at position 47 with alanine or asparagine in transforming growth factor alpha had no effect, but that replacement with serine or glutamic acid sharply reduced biological activity (see the abstract). Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). The nucleic acids encoding all these

mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize to SEQ ID NO:5. Making all possible single amino acid substitutions in an 118 amino acid long protein like that encoded by SEQ ID NO:5 would require making and analyzing 19^{118} nucleic acids; these proteins would have 99.1% identity to SEQ ID NO:12. Because nucleic acids that hybridize to SEQ ID NO:5 could have amino acid substitutions, many more than 19^{118} nucleic acids would need to be made and analyzed. Guo et al. (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing proteins with many amino acid substitutions that also have anti-microbial activity would require undue experimentation.

As the specification does not describe the transformation of any plant with a nucleic acid that hybridizes to SEQ ID NO:5, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with microbe-resistance, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

11. Claims 5-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of nucleic acids that hybridize to SEQ ID NO:5 and that encode a protein with "substantially similar activity to that encoded by SEQ ID NO:5". In contrast, the specification only describes a coding sequences from Dahlia that comprise SEQ ID NO:1-5. Applicant does not describe other nucleic acids encompassed by the claims, and the structural and functional features that distinguish all such nucleic acids from other nucleic acids are not provided.

No description/evidence is provided as to the function of the encoded protein. The phrase "substantially similar activity to that encoded by SEQ ID NO:5" does not indicate which activity of which protein encoded by open reading frame of SEQ ID NO:5 the claim refers.

Hence, Applicant has not, in fact, described nucleic acids that hybridize to SEQ ID NO:5 within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 5-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 5-7 lack antecedent basis for the limitation "the sequence" in lines 9, 13 and 3, respectively.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation "plastids", and the claim also recites "chloroplasts" which is the narrower statement of the range/limitation.

Claim 7 lacks antecedent basis for the limitation "the protein encoding regions".

Claim 7 lacks antecedent basis for the limitation "polynucleotide according to any preceding claim" as claims 2-4 are drawn to a polynucleotide sequence".

Claims 8-11 and 14-15 lack antecedent basis for the limitation "polynucleotide according to any one of claims 1 to 6" as claims 2-4 are drawn to a polynucleotide sequence".

Claim 9 lacks antecedent basis for the limitation "the thus modified polynucleotide" in line 8.

Claim 11 lacks antecedent basis for the limitation "the said transformed plant tissue" in lines 2-3.

Claim 11 is indefinite for claiming plant tissue and material derived from the plant. If one only had material derived from the plant, would it be encompassed within the claim?

Claim 12 is indefinite for plants. If one only had one plant would it be encompassed within the claim?

Claim 13 lacks antecedent basis for the limitations "the progeny" in line 1 and "the polynucleotide sequence" in lines 2-3.

Claim 13 is indefinite for claiming progeny, seeds and "such progeny". If one only had seeds, would they be encompassed within the claim? Would one seed be so encompassed?

Claim 14 lacks antecedent basis for the limitations "the thus transformed material" in line 6 and "the thus selected material" in line 7.

14. Claim 15 provides for the use of a polynucleotide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 5-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Broekaert et al (1996, US Patent 5,538,525).

Broekaert et al teach several nucleic acids that encode plant anti-microbial proteins, wherein the nucleic acids would hybridize to SEQ ID NO:5 and bases 177 to 326 of SEQ ID NO:5 under the conditions recited in the instant claims 5 and 6 (see search results). Broekaert et al also teach plants transformed with the nucleic acids, and a method of using the nucleic acids to make pathogen resistant plants (column 26, line 18, to column 28, line 2).

17. Claims 1-4 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid comprising SEQ ID NO:5 or bases 177-326 or 327-446 of SEQ ID NO:5.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

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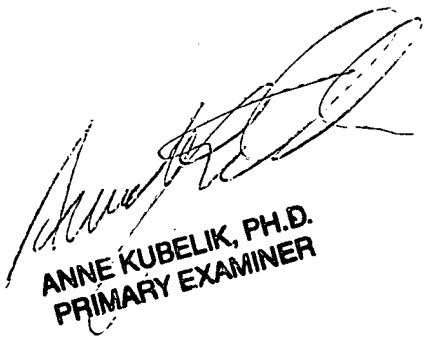
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
March 30, 2005



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; STREET: 1100 NEW YORK AVENUE, N.W.
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; ZIP: 20005
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/971,982
; FILING DATE: 17-No. 6187904-1997
; CLASSIFICATION: <Unknown>
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/002,480
; FILING DATE: 04-JAN-1993
; ATTORNEY/AGENT INFORMATION:
; NAME: KOKULIS, PAUL N.
; REGISTRATION NUMBER: 16,773
; REFERENCE/DOCKET NUMBER: 99042/SEE.36525/US/A
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 202-861-3000
; TELEFAX: 202-822-0944
; INFORMATION FOR SEQ ID NO: 31:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 150 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: both
; TOPOLOGY: linear
; MOLECULE TYPE: cDNA
; SEQUENCE DESCRIPTION: SEQ ID NO: 31:
US-08-971-982-31

Query Match 22.3%; Score 99.4; DB 3; Length 150;
Best Local Similarity 79.2%; Pred. No. 4.6e-21;
Matches 118; Conservative 0; Mismatches 31; Indels 0; Gaps 0;

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RESULT 5
US-08-377-687-33
; Sequence 33, Application US/08377687
; Patent No. 5538525
; GENERAL INFORMATION:
; APPLICANT: BROEKAERT, WILLEM F.
; APPLICANT: CAMMUE, BRUNO P.A.
; APPLICANT: OSBORN, RUPERT W.
; APPLICANT: REES, SARAH B.
; APPLICANT: TERRAS, FRANKY R.G.
; APPLICANT: VANDERLEYDEN, JOZEF
; TITLE OF INVENTION: BIOCIDAL PROTEINS
; NUMBER OF SEQUENCES: 59
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: CUSHMAN DARBY & CUSHMAN
; STREET: 1100 NEW YORK AVENUE, N.W.
; CITY: WASHINGTON
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; COUNTRY: USA
; ZIP: 20005
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/377,687
; FILING DATE:
; CLASSIFICATION: 800
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/002,480
; FILING DATE: 04-JAN-1993
; ATTORNEY/AGENT INFORMATION:
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; TELEFAX: 202-822-0944
; INFORMATION FOR SEQ ID NO: 33:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 150 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: both
; TOPOLOGY: linear
; MOLECULE TYPE: cDNA
US-08-377-687-33

Query Match 20.5%; Score 91.4; DB 1; Length 150;
Best Local Similarity 75.8%; Pred. No. 1.4e-18;
Matches 113; Conservative 0; Mismatches 36; Indels 0; Gaps 0;

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Db      121 AAGCATATGTGCTTCTGCTACTTCAACTG 149
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not Nucleic SEQ ID 6

RESULT 6
US-08-777-192-33
; Sequence 33, Application US/08777192
; Patent No. 5824869
; GENERAL INFORMATION:
; APPLICANT: BROEKAERT, WILLEM F.
; APPLICANT: CAMMUE, BRUNO P.A.
; APPLICANT: OSBORN, RUPERT W.
; APPLICANT: REES, SARAH B.
; APPLICANT: TERRAS, FRANKY R.G.
; APPLICANT: VANDERLEYDEN, JOZEF
; TITLE OF INVENTION: BIOCIDAL PROTEINS
; NUMBER OF SEQUENCES: 59
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; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/777,192
; FILING DATE:
; CLASSIFICATION: